

The Examiner rejected claims 1, 6-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by De Jong et al. Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-18 and 33-35 under 35 U.S.C. § 103(a) as being unpatentable over Bjorck et al., Ho et al., Clark et al., Zikakis, Antrim et al., and De Jong et al. in view of Reddy et al. Applicants respectfully traverse this rejection.

### 35 U.S.C. § 112 Rejection

The Examiner rejected claim 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter with Applicants regard as the invention. Specifically, the Examiner asserts that the phrase "the second portion begin sterilized" only says what you do to the portion but does not clearly indicate what it is. Claim 11 has been amended to clarify what the portion is as opposed to what process has been carried out on it. Applicants respectfully assert therefore that this rejection should be withdrawn.

### 35 U.S.C. § 102 Rejections

The Examiner rejected claims 33-34 under 35 U.S.C. § 102(b) as being anticipated by Bjorck et al.

The Examiner rejected claims 1, 7-8, 11, 15, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Cooray et al.

The Examiner rejected claims 1-4, 6-11, 14-17, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Clark et al.

The Examiner rejected claims 1-17 and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Ho et al.

The Examiner rejected claims 33-34 under 35 U.S.C. § 102(b) as being anticipated by Zikakis.

The Examiner rejected claims 33-34 under 35 U.S.C. § 102(b) as being anticipated by Antrim et al.

The Examiner rejected claims 1, 6-10, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by De Jong et al.

Claims 33 and 34 have been cancelled herein, obviating the rejections thereof. The newly amended and added claims are limited to formula feed for administration to a human infant as a breast milk substitute. It is submitted that such an amendment has basis on page 3, lines 24 to 25 of the description where it is stated that "Babies who are not breast-fed are fed what is referred to herein as a formula feed". Applicants respectfully assert that the intended use of the composition adds patentable weight because it more fully defines the composition.

While it is true that cow's milk may be used as a starting ingredient for the formulation of a formula feed, it is submitted that cow's milk per se whether pasteurized, powdered or raw is not suitable for administration to a human infant as a breast milk substitute and does not therefore fall within the scope of the newly amended and added claims. The term "nutritionally complete" has been removed from the claims because it has been subsumed in the phrase "for administration to a human infant as a breast milk substitute". The requirement for the formula feed to be suitable as a breast milk substitute defines the requirements of the nutritional content of the feed.

) Not true

Cooray et al (1995) discloses compositions consisting of XOR and milk, or XOR and butter, neither of these compositions would be suitable for administration to a human infant as a breast milk substitute.

The compositions of Clark et al (1976) are experimental compositions used to study XOR absorption. They are administered to adult rats and are not suitable as a human breast milk substitute. The compositions are saline or half cream/half milk compositions. Saline based compositions are not suitable for administration to human infants as a breast milk substitute because they do not provide any nutrition to the infant. Milk or cream based compositions will contain nutrients but not in the correct amounts and ratios for the composition to qualify as a breast milk substitute for human infants. The compositions of Ho et al. are similar to those of Clark.

De Jong et al (1998) discloses a wide range of food products including raw milk but there is no disclosure of the use of XOR in a formulation suitable for administration to a human infant as a substitute for breast milk.

Applicants respectfully assert that none of the cited references teach a composition which could be used as a formula feed for administration to a human infant

as a breast milk substitute. In light of the above comments and amendments Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 102(b) be withdrawn.

**35 U.S.C. § 103 Rejection**

The Examiner rejected claims 1-18 and 33-35 under 35 U.S.C. § 103(a) as being unpatentable over Bjorck et al., Ho et al., Clark et al., Zikakis, Antrim et al., and De Jong et al. in view of Reddy et al.

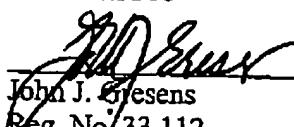
Applicants respectfully assert that the newly amended claims are not rendered obvious by the cited references or combinations thereof because none of these references teach or suggest a composition that is nutritionally complete for administration to a human infant. Reddy et al does not disclose that XOR may be beneficial when added to human infant formula feed, only that it can be added to animal feed to improve health and reduce fecal odors. Therefore, because the cited references or combinations thereof do not teach or suggest all of the claim limitations, Applicants respectfully request the withdrawal of this rejection.

**Conclusion**

In view of the amendments and comments presented herein, favorable reconsideration in the form of a Notice of Allowance is respectfully requested.

Respectfully submitted,  
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Version with Markings to Show Changes MadeIn the Claims

Please amend claims 1, and 11 as follows:

1. (Twice Amended) A formula feed [for administration to a human or animal, the formulation] comprising active xanthine oxidoreductase (XOR), wherein said formula feed is for administration to a human infant as a breast milk substitute [nutritionally complete].
11. (Thrice Amended) A kit for use in the preparation of a formula feed according to claim 1, comprising a first and second portions, the first portion including active XOR and the second portion being [sterilized] sterile.

Please add new claims 38 and 39 as follows:

38. (New) A formula comprising active xanthine oxidoreductase (XOR), wherein said formula feed is in the form of a powder and is for administration to a human infant as a breast-milk substitute.
39. (New) A formula feed comprising active xanthine oxidoreductase (XOR), wherein said formula feed is for administration to a human infant as a breast milk substitute and is nutritionally complete.